

BIOFREEZE- menthol spray
Performance Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Biofreeze Spray

Drug Facts

Active Ingredients:

Menthol 10.5%

Purpose:

Cooling Pain Relief

Uses

Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis
backache strains and sprains

Warnings

For external use only.

Flammable:

Keep away from excessive heat or open flame.

Contents Under Pressure. Do Not Puncture Or Incinerate Do Not Store At Temperature Above 120°F

Ask a Doctor Before using If You have:

Sensitive skin

When Using This Product

Avoid contact with the eyes or mucous membranes; Do not apply to wounds or damaged skin; Do not use with other ointments, creams, sprays or liniments; Do not apply to irritated skin or if excessive irritation develops; Do not bandage; Wash hands after use with cool water; Do not use with heating pad or device; Store in a cool dry place

Stop Use And Ask A Doctor If:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions:

Adults and children 12 years of age and older: Spray on to the affected areas not more than 4 times daily; massage not necessary

Children under 12 years of age: Consult physician

Inactive Ingredients

Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

Questions or Comments:

1-800-246-3733

Package Labeling:

COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

PRESS DOWN FIRMLY TO ACTIVATE SPRAYER FOR FIRST USE
NDC 59316-114-10

360° SPRAY

APPLY FROM ANY ANGLE EVEN SPRAYS UPSIDE DOWN

Does not contain NSAIDs, Ibuprofen, Aspirin, or Salicylate

Manufactured in the USA
No Animal Testing

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1245 Home Avenue
Akron, OH 44310 www.biofreeze.com
13454 REV 5

For best results, use Biofreeze® in combination with care from a health professional. Find one in your area at Biofreeze.com.

DOT SP 15792 M5655

LOT

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BIOFREEZE
COOL THE PAIN
SPRAY
FAST ACTING
MENTHOL PAIN RELIEF

3 FL. OZ. / 88 mL



BIOFREEZE

COOL THE PAIN

SPRAY

FAST ACTING
MENTHOL PAIN RELIEF

1.6 FL. OZ. / 47.3 mL

COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS
LONG-LASTING • VANISHING SCENT • PARABEN-FREE
*Trusted by pharmacists, physical therapists, chiropractors, massage therapists and podiatrists



Does not contain NSAIDs, Ibuprofen, Aspirin, or Salicylate
©2019 Performance Health, LLC, 1245 Home Avenue, Akron, OH 44310
www.biofreeze.com
BUSASN16-001 REV9
Manufactured in the USA
No Animal Testing

For best results, use Biofreeze® in combination with care from a health professional. Find one in your area at Biofreeze.com.

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NDC 59316-114-30



BIOFREEZE

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	105 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (UNII: O80TY208ZW)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

CHAMOMILE (UNII: FGL3685T2X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
ALCOHOL (UNII: 3K9958V90M)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPERUS COMMUNIS WHOLE (UNII: 464910T5N9)	
BERRY (UNII: FV3431923Z)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-114-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2016	

Labeler - Performance Health LLC (794324061)

Revised: 6/2019

Performance Health LLC